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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,442	04/13/2000	TIMO LAAKSO	003300-634	7079

7590 03/22/2004

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EXAMINER
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LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/22/2004

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/529,442

Applicant(s)

LAAKSO ET AL.

Examiner

Neil Levy

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/28/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 10-31, 33-76 is/are pending in the application.
- 4a) Of the above claim(s) 43, 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 8, 10-31, 33-76 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicant should identify status on P. 1, if priority is desired.

Claims 43, 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7/28/03.

Claims 1-5, 7, 8, 10, 11, 13-31, 33-42, 45-47, 50-69, 72-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tice et al 5407609 in view of Okada et al 4,652,441.

Tice dissolves a biodegradable polymer preferably polylactide – polyglycolide (col. 4, lines 24-29) in solvent of ethyl acetate for instance (col. 3, lines 49-63), and then, prepares a dispersion of active agent in the solvent/polymer (col. 4, lines 30-33), the actives being any numbers of agents (col. 4, line 35 – line 49, col. 4) of the instant claims. However the continuous phase is represented as emulsion of polyvinyl alcohol (PVA) or Polyvinyl pyrrolidone (PVD), rather than the instant polyethylene glycol (PEG).

Okada also utilizes the instant biodegradable lactide homo and copolymers to produce microcapsules, (col. 5, top) and shows equivalence of PEG and PVA or PVP (col. 4, lines 40-47). The actives are those (col. 2, - col. 4), instantly claimed, and of Tice.

Surfactants are utilized, col. 7, bottom, as is preparation by stirring mixing gentrifying and freezing (col. 8, top) to produce 0.5-400 micron microcapsules (col. 8, line 33-41) for parenteral injection (col. 8, lines 63-68). One of ordinary skill in the microcapsule art would have for and it obvious to prepare the microcapsule of Tice,

modified with selection of an aqueous continuous process medium of PVA, PVP, or equivalently, PEG.

Applicant's arguments filed on 7/28/03 have been fully considered but they are not persuasive. Applicant's arguments have been considered, and references reviewed. The prior art of biodegradable microcapsule formation is well established – glycolide/lactide polymers well known, as is the preparation. Tice, and Okada, are representative of these methods, as is the use of particularly, desired drugs, pesticides or other actives, with stability and release characteristics, for instance, driving the particular size, shape, active agent, and choice of compatible adjuvant materials and thus preparation methods. Tice shows these, Okada and others cited by applicant.

Claims 6, 12, 48, 49, 70, 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Levy/LR  
March 9, 2004



NEIL S. LEVY  
PRIMARY EXAMINER